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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,451	07/30/2003	Katia Vancompernelle	2676-6045US	5403

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EXAMINER

FRONDA, CHRISTIAN L

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 07/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/630,451

Applicant(s)

VANCOMPERNOLLE, KATIA

Examiner

Christian L. Fronda

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 May 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 3-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,18,21 and 22 is/are rejected.
- 7) ☒ Claim(s) 19 and 20 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Claims 1, 2, and 18-22 are under consideration in this Office Action.
2. The rejection of claims 1, 2, and 18-20 under 35 U.S.C. 112, second paragraph, as being indefinite has been withdrawn in view of applicants' amendment filed 05/11/2005.
3. The rejection of claim 18 under 35 U.S.C. 112, 35 U.S.C. 112, first paragraph, failing to comply with the enablement requirement has been withdrawn in view of applicants' amendment filed 05/11/2005.

Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
5. Claims 1, 18, 21, 22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants' arguments filed 05/11/2005 have been fully considered but they are not persuasive. Applicants' position is that the specification provides at least one species of an enzyme capable of protein glycation and identified one common characteristic thereof, specifically, the protein methylglyoxal modifying activity. The Examiner respectfully disagrees for reasons of record as supplemented below.

The claims are genus claims that are directed toward any polypeptide of any biological source and amino acid sequence and structure having protein methylglyoxal modifying activity, and any phosphorylated glyoxalase I of any biological source and amino acid sequence and structure. The scope of the claims includes many enzymes with widely differing structural, chemical, and physical characteristics. Furthermore, the genus is highly variable because a

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significant number of structural differences between genus members exists. No patentable weight is given to the process of producing the claimed polypeptide as recited in claims 18 and 22 since there is no structural limitations from the process of producing the claimed polypeptide.

The specification discloses a human glyoxalase I consisting of the amino acid sequence of SEQ ID NO: 1. However, the specification and the art do not provide any amino acid sequence and structure which is common to all the members of the claimed genus.

In the evaluation of the claims for compliance with the written description requirement of 35 U.S.C. 112, of particular relevance is 66 FR 1099, Friday, January 5, 2001, which states:

"Eli Lilly explains that a chemical compound's name does not necessarily convey a written description of the named chemical compound, particularly when a genus of compounds is claimed. *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1405. The name, if it does no more than distinguish the claimed genus from all others by function, does not satisfy the written description requirement because "it does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406. Thus *Eli Lilly* identified a set of circumstances in which the words of the claim did not, without more, adequately convey to others that applicants had possession of what they claimed." (see p. 1100, 1st column, line 47 to 2nd column, line 2, attached to this office action).

In view of the above considerations, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed genus of any polypeptide of any biological source and amino acid sequence and structure having protein methylglyoxal modifying activity, and any phosphorylated glyoxalase I of any biological source and amino acid sequence and structure.

Claim Rejections - 35 U.S.C. § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1, 2, 18, 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ranganathan et al. (J Biol Chem. 1993 Mar 15;268(8):5661-7; PTO 1449) in view of Pestka et al. (Protein Expr Purif. 1999 Nov;17(2):203-14; PTO 892).

Applicants' arguments filed 05/11/2005 have been fully considered but they are not persuasive. Applicants position is that the amended claims define over the combination of references stated in the previous Office Action. The Examiner respectfully disagrees for reasons of record as supplemented below.

As stated in the previous Office Action, Ranganathan et al. teach the human colon glyoxalase I which is a mammalian glyoxalase I enzyme that has an amino acid sequence that is 100 % identical to SEQ ID NO: 1. Since the amino acid sequence of the mammalian glyoxalase I enzyme taught by Ranganathan et al. is 100 % identical to SEQ ID NO: 1 and in absence of facts to the contrary, the taught mammalian glyoxalase I is expected to have the recited protein methylglyoxal modifying activity.

Since the Patent Office does not have the facilities for examining and comparing the claimed polypeptide to the glyoxalase I enzyme taught by Ranganathan et al., the burden is on applicant to show that the prior art glyoxalase I enzyme is different from the claimed polypeptide. See *In re Best*, 562 F.2d 1252, 195 USPQ 430(CCPA 1977).

In regard to claim 22, no patentable weight is given to the process for making the glyoxalase I since the process does not provide additional structural limitations to the claimed glyoxalase I. For the reasons of record and above, the claims are obvious over Ranganathan et al. in view of Pestka et al.

Conclusion

8. No claim is allowed.

9. Claims 19 and 20 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L Fronda whose telephone number is (571)272-0929. The examiner can normally be reached Monday-Friday between 9:00AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura N Achutamurthy can be reached on (571)272-0928. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

12. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CLF



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